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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/576,581	04/20/2006	Hitoshi Ban	0020-5482PUS1	2390

2292 7590 01/13/2009  
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EXAMINER
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O'DELL, DAVID K

ART UNIT	PAPER NUMBER
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1625

NOTIFICATION DATE	DELIVERY MODE
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01/13/2009

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/576,581	<b>Applicant(s)</b> BAN ET AL.	
	<b>Examiner</b> David K. O'Dell	<b>Art Unit</b> 1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 20 April 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-28 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### DETAILED ACTION

1. This application is a 371 of PCT/JP04/15773 filed 10/19/2004 and claims priority to JAPAN 2003-361256 filed 10/21/2003.

Claims 1-28 are pending.

2. *Election/Restrictions*

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, Claims 1-26 drawn to compounds and compositions reading on X is N, m is 2, n is 2, p is 0, R<sup>1</sup> is phenyl, Z is phenyl with the proviso that none of the substituents on the X ring form bridges or double bonds, drawn to 1,4-diphenyl piperidines, shown as structure **I** in Figure 1. If this group is elected, a further election of a single disclosed species is also required. Further restriction based on the election may be made.

Group II, Claims 1-26 drawn to compounds and compositions reading on X is N, m is 2, n is 2, p is 0, R<sup>1</sup> is phenyl, Z is a heteroaryl, with the proviso that none of the substituents on the X ring form bridges or double bonds, drawn to 1-phenyl-4-heteroaryl-piperidines, shown as structure **II** in Figure 1. If this group is elected, a further election of a single disclosed species is also required. Further restriction based on the election may be made.

Group III, Claims 1-26 drawn to compounds and compositions reading on X is N, m is 2, n is 2, p is 0, Z is phenyl, R<sup>1</sup> is a heteroaryl, with the proviso that none of the substituents on the X ring form bridges or double bonds, drawn to 1-heteroaryl-4-phenyl-piperidines, shown as structure **III** in Figure 1. If this group is elected, a further election of a single disclosed species is also required. Further restriction based on the election may be made.

Group IV, Claims 1-26 drawn to compounds and compositions reading on X is CR<sup>15</sup>, R<sup>15</sup> is NR<sup>19</sup>R<sup>20</sup>, and R<sup>19</sup> and R<sup>20</sup> form piperazine, m is 2, n is 2, p is 0, Z is phenyl, with the proviso that none of the substituents on the X ring form bridges or double bonds, drawn to 1-piperazinyl-4-phenyl-cyclohexanes, shown as structure **IV** in Figure 1. If this group is elected, a further election of a single disclosed species is also required. Further restriction based on the election may be made.

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Group V, Claims 1-26 drawn to compounds and compositions reading on X is CR<sup>15</sup>, R<sup>15</sup> is NR<sup>19</sup>R<sup>20</sup>, and where R<sup>19</sup> and R<sup>20</sup> do not form a ring, m is 2, n is 2, p is 0, Z is phenyl, , with the proviso that none of the substituents on the X ring form bridges or double bonds, drawn to 1-amino-4-phenyl-cyclohexanes, shown as structure **V** in Figure 1. If this group is elected, a further election of a single disclosed species is also required. Further restriction based on the election may be made.

Group VI, Claims 1-26 drawn to compounds and compositions reading on X is CR<sup>15</sup>, R<sup>15</sup> is NR<sup>19</sup>R<sup>20</sup>, and where R<sup>19</sup> and R<sup>20</sup> form a piperidine ring, m is 2, n is 2, p is 0, Z is phenyl, , with the proviso that none of the substituents on the X ring form bridges or double bonds, drawn to 1-piperidinyl-4-phenyl-cyclohexanes, shown as structure **VI** in Figure 1. If this group is elected, a further election of a single disclosed species is also required. Further restriction based on the election may be made.

Group VII, Claims 1-26 drawn to compounds and compositions reading on X is N, m is 2, n is 2, p is other than 0, R<sup>1</sup> is phenyl, Z is a phenyl drawn to 1-aralkyl-4-phenyl-piperidines, with the proviso that none of the substituents on the X ring form bridges or double bonds, shown as structure **VII** in Figure 1. If this group is elected, a further election of a single disclosed species is also required. Further restriction based on the election may be made.

Group VIII, Claims 1-26 drawn to compounds and compositions reading on X is N, m is 2, n is 2, p is 0, Z is phenyl, R<sup>1</sup> is a phenyl, where on the X ring the carbons adjacent to the nitrogen form a bridging ethyl group, drawn to diphenyl-tropanes, shown as structure **VIII** in Figure 1. If this group is elected, a further election of a single disclosed species is also required. Further restriction based on the election may be made.

Group IX, Claims 1-26 drawn to compounds and compositions reading on X is N, m is 2, n is 2, p is 0, Z is phenyl, R<sup>1</sup> is a phenyl, where on the X ring the carbons adjacent to the nitrogen form a bridging propyl group, drawn to diphenyl-azabicyclononanes, shown as structure **IX** in Figure 1. If this group is elected, a further election of a single disclosed species is also required. Further restriction based on the election may be made.

Group X, Claims 1-26 drawn to compounds and compositions reading on X is CR<sup>15</sup>, R<sup>15</sup> is NR<sup>19</sup>R<sup>20</sup>, and R<sup>19</sup> and R<sup>20</sup> form morpholine, m is 2, n is 2, p is 0, Z is phenyl, with the proviso that none of the substituents on the X ring form bridges or double bonds, drawn to 1-morpholinyl-4-phenyl-cyclohexanes, shown as structure **X** in Figure 1. If this group is elected, a further election of a single disclosed species is also required. Further restriction based on the election may be made.

Group XI, Claims 1-26 drawn to compounds and compositions reading on X is N, m is 2, n is 2, p is 0, Z is phenyl, R<sup>1</sup> is a aralkyl, where on the X ring the carbons adjacent to the nitrogen form a bridging ethyl group, drawn to N-aralkylphenyl-tropanes, shown as structure **XI** in Figure 1. If this group is elected, a further election of a single disclosed species is also required. Further restriction based on the election may be made.

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Group XII, Claims 1-26 drawn to compounds and compositions reading on X is N, m is 3, n is 2, p is 0, R<sup>1</sup> is phenyl, Z is phenyl with the proviso that none of the substituents on the X ring form bridges or double bonds, drawn to 1,4-diphenyl azepines, shown as structure **XII** in Figure 1. If this group is elected, a further election of a single disclosed species is also required. Further restriction based on the election may be made.

Group XIII, Claims 1-26 drawn to compounds and compositions reading on X is N, m is 2, n is 2, p is 0, Z is NR<sup>9</sup>R<sup>10</sup>, where R<sup>9</sup> and R<sup>10</sup> form piperidine, and R<sup>1</sup> is phenyl with the proviso that none of the substituents on the X ring form bridges or double bonds, drawn to 1-piperidinyl-4-phenyl-piperidines, shown as structure **XIII** in Figure 1. If this group is elected, a further election of a single disclosed species is also required. Further restriction based on the election may be made.

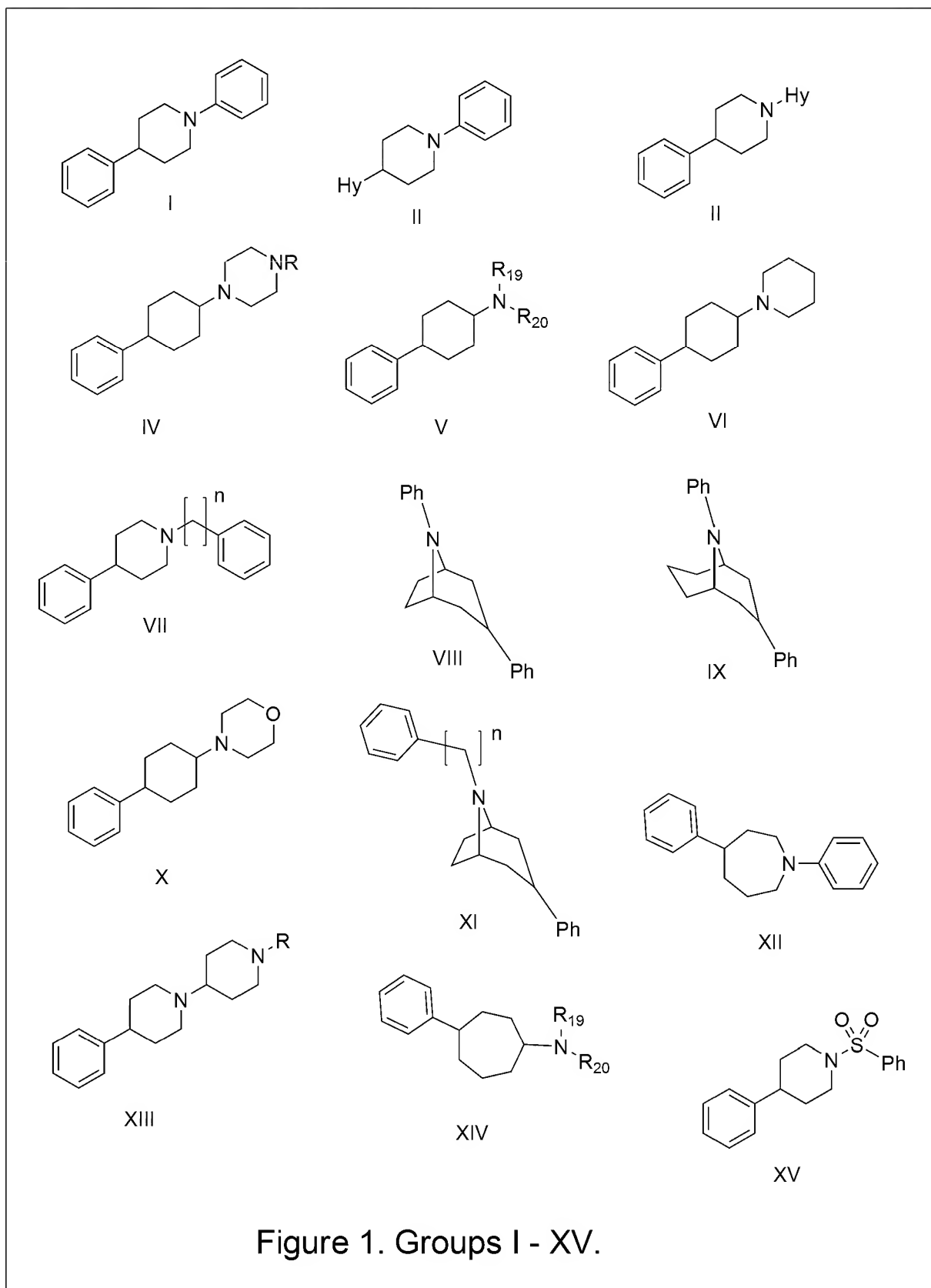
Group XIV, Claims 1-26 drawn to compounds and compositions reading on X is CR<sup>15</sup>, R<sup>15</sup> is NR<sup>19</sup>R<sup>20</sup>, and where R<sup>19</sup> and R<sup>20</sup> do not form a ring, m is 3, n is 2, p is 0, Z is phenyl, with the proviso that none of the substituents on the X ring form bridges or double bonds, drawn to 1-amino-4-phenyl-cycloheptanes, shown as structure **XIV** in Figure 1. If this group is elected, a further election of a single disclosed species is also required. Further restriction based on the election may be made.

Group XV, Claims 1-26 drawn to compounds and compositions reading on X is N, m is 2, n is 2, p is 0, R<sup>1</sup> is a phenylsulfonamide, Z is a phenyl, with the proviso that none of the substituents on the X ring form bridges or double bonds, drawn to 1-phenylsulfonamide-4-phenyl-piperidines, shown as structure **XV** in Figure 1. If this group is elected, a further election of a single disclosed species is also required. Further restriction based on the election may be made.

Group XVI, Claims 1-26 drawn to compounds and compositions reading on compounds other than those of groups I-XV. If this group is elected, a further election of a single disclosed species is also required. Further restriction based on the election will be made.

Group XVII, Claim 27, drawn to methods of treating diseases, , limited in scope to one of the compounds of groups I-XVI. If this group is elected, a single disclosed disease and a single disclosed species useful in treating diseases, is also required. Further restriction based on the election may be made.

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**PLEASE NOTE:** Claim 28 is a non-statutory use claim and is withdrawn from consideration. Cancellation is recommended.

The inventions listed as Groups I-XVII do not relate to a single general inventive concept under 35 USC 121 or PCT Rule 13.1 because:

**PCT Rule 13.1** states that the international application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept (“requirement of unity of invention”).

**PCT Rule 13.2** states that the unity of invention referred to in Rule 13.1 shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features.

Annex B, **Part 1(a)**, indicates that the application should relate to only one invention, or if there is more than one invention, inclusion is permitted if they are so linked to form a single general inventive concept.

Annex B **Part 1(b)**, indicates that “special technical features” means those technical features that as a whole define a contribution over the prior art.

Annex B **Part 1(c)**, further defines independent and dependent claims. Unity of invention only is concerned in relation to independent claims. Dependent claims are defined as a claim that contains all the features of another claim and is in the same category as the other claim. The category of a claim refers to the classification of claims according to subject matter e.g. product, process, use, apparatus, means, etc.

Annex B **Part 1(e)**, indicates that the permissible combinations of different categories of claims. **Part 1(e)I**, states that inclusion of an independent claim for a given product, an independent claim for a process specially adapted for the manufacture of the said product, and an independent claim for a use of the said product is permissible.

Annex B, **Part 1(f)**, indicates the “Markush practice” of alternatives in a single claim. **Part 1(f)I**, indicates the technical relationship and the same or corresponding special technical feature is considered to be met when (A) all alternatives have a common property or activity, and (B) a common structure is present or all alternatives belong to a recognized class of chemical compounds. Further defining (B), Annex B, **Part 1(f)(i-iii)**, the common structure must; a) occupy a large portion of their structure, or b) the common structure constitutes a structurally distinctive portion, or c) where the structures are equivalent and therefore a recognized class of chemical compounds, each member could be substituted for one another with the same intended result. That is, with a common or equivalent structure, there is an expectation relationship and the corresponding special technical feature result from a common (or equivalent) structure that is responsible for the common activity (or property). **Part 1(f) iv**, indicates that when all alternatives of a Markush grouping can be differently classified, it shall not, taken alone, be considered justification for finding a lack of unity. **Part 1(f)v**, indicates that “When dealing with alternatives, if it can be shown that at least *one* Markush alternative is not novel over the prior art, the question of unity of invention shall be reconsidered by the examiner”

In the instant case, the majority of the Markush alternatives are not novel because countless prior art references, such as the 31 documents cited in the international search report as

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anticipatory X references, describe the compounds of the instant claims, thus the lack of a special technical feature is apparent.

Inventions I-XVI and XVII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case at least the method of treating atherosclerosis can be practiced with diet and exercise.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is *presented prior to* final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be **allowable**, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See “Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*; *In re Brouwer* and 35 U.S.C. § 103(b),” 1184 O.G. 86 (March 26, 1996).

Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include all the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01. Filing of appropriate terminal disclaimer in anticipation of a rejoinder may speed prosecution and the process of rejoinder.



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3. In addition to the selection of an elected group applicant is required to elect a species. All claims are generic to the following disclosed patentably distinct species: the compounds of the specification. The species are independent or distinct because as disclosed the different species have mutually exclusive characteristics for each identified species. In addition, these species are not obvious variants of each other based on the current record.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

There is an examination and search burden for these patentably distinct species due to their mutually exclusive characteristics. The species require a different field of search (e.g., searching different classes/subclasses or electronic resources, or employing different search queries); and/or the prior art applicable to one species would not likely be applicable to another species; and/or the species are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

**Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected species,** including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

The election of the species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the election of species requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected species.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the

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examiner finds one of the species unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other species.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141.

### *Conclusion*

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David K. O'Dell whose telephone number is (571)272-9071. The examiner can normally be reached on Mon-Fri 7:30 A.M.-5:00 P.M EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres can be reached on (571)272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

D.K.O.

/Rita J. Desai/  
Primary Examiner, Art Unit 1625

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